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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	11

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/950,963	DREWES ET AL	
	Examiner	Art Unit	
	Jeffrey S Lundgren	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *11 May 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *13-17 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 18-34 and 36-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☑ Interview Summary (PTO-413) Paper No(s) 11 .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

BB 7/17/00

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 18-20, 23, 24, and 36, are rejected under 35 U.S.C. 102(b) as being anticipated by Brecht et al (Anal. Chim. Acta *311*, 289-299, **1999**) for the reasons made of record in the Office action mailed on September 3, 1999 (paper No. 7).

Applicants arguments have been fully considered and are not found persuasive for the following reasons.

Applicant asserts that the disclosure of Brecht et al. does not anticipate the claimed invention because Brecht et al. was not in possession of a "true" laminar flow cell.

As communicated in the previous Office action, Brecht et al., clearly indicate that there are two cell types considered in their disclosure of the *Setup*:1) a "laminar flow" cell system and 2) a "wall jet" flow cell system. Brecht clearly distinguish the performance differences between the types of cells on page 295 (section 3.3), stating that the laminar flow cell had superior performance, and was the cell used for all other experiments. On page 296,

Brecht et al., clearly demonstrate that improved mass transport to the sensor surface is responsible for the increased signal, an inherent property of laminar flow:

> "Results (Fig. 7 anf Fig. 8) show clearly, that the signal can be increased by improvement of mass transport to the sensor surface... At least in part, the introduction of irregularities in flow characteristics affect not only the [test-to-test] reproducibility but also the noise of the binding curves."

It is evident that Brecht et al., recognizes that their cell is not a true "laminar flow" cell. However, it is made clear from the disclosure of Brecht et al., as the ordinary artisan would recognize, that a cell with reduced flow irregularities, and more "laminar-like" flow characteristics would be an improvement over "wall jet" flow systems, and thus the ordinary artisan need not turn to Olson for such guidance.

The rejection is maintained.

3. Claims 3-6, 9, 21, 22, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kline et al. (U.S. Patent No. 5,459,078, October 17, 1995) for the reasons made of record in the Office Action mailed on September 3, 1999 (paper No. 7).

Applicants arguments have been fully considered and are not found persuasive for the following reasons.

Applicant argues that the invention of the instant application is a device comprising an optically functional layer, wherein optically functional layer is defined as being a layer "which can produce a signal upon the binding of an analyte to a receptive layer", and points to page 10, lines 4-23 of the

specification. Applicant asserts in the Response to Office Action received on May 11, 2000 (paper No. 10), that the signal measured with the inventive device is limited to the physical events measurable by reflectance, transmittance, or polarization of light.

Applicants' definition of the "optically functional layer" is in fact met by the teachings of Kline et al. Applicant broadly defines the aforementioned phrase, which states (page 10 of the specification):

> "By 'optically functional layer' is meant a layer which can produce a signal upon the binding of analyte to a receptive layer. The layer may have one or more coatings, including the base layer with or without an antireflective layer, designed to modify the optical properties of the support material so that the desired degree of reflectivity, transmittance, and/or absorbance is suited to the final assay configuration. The optically functional layer may attenuate one or more, or a range of wavelengths of light so that a result is observable visually or by instrumental analysis in the final device upon analyte binding"

The optically functional layer of Kline et al. does embody the use of indicator reagents in the sensing process with the sensor device (column 9, lines 34 to 62). The detection schemes include assays based on competitive binding assays, wherein the target analyte and indicator reagent compete for an immobilized recognition site. Although in a competitive binding assay the signal is inversely proportional to the concentration of the analyte bound to the surface, there exists "a layer" that produces a signal when analyte binds to the "receptive layer", wherein that layer is designed to modify the optical properties of the support material (i.e., absorbance of one color range of light through the indicator, and reflectance of the light difference). For example, in the blank run of a competitive binding assay where there is no analyte present, only standard reagents and the indicator reagent are used (such as the Kline device), and a

"full-color" signal would be measured, which determines a relative level of signal one observes in the absence of analyte. However, when a sample is introduced to the regenerated (or new but identical) sensor device that contains a detectable amount of analyte, the same concentration of indicator reagent, and other reagents, less indicator reagent binds to the receptive layer, as a result of analyte binding to the receptive layer, and a signal different than that of the blank run is detected. Both Kline et al. and Applicants' devices meet the definition of the optically functional layer as it is presented in the specification. Inherently, every sensor produces a signal *relative* to some reference point, including both the sensor of Kline et al., and Applicants' claimed device. Therefore, in the device of Kline, a "layer" produces a signal upon the binding of analyte to a receptive layer, albeit a decrease in signal. Applicant does not limit the definition of an optically functional layer to a layer of a device which measures the refractive index differences between the analyte-free layer and the analyte-bound layer, nor does the definition of the phrase "optionally functional layer" limit the invention to a device wherein the detectable changes in signal result *directly* from analyte binding to the receptive layer.

The rejection is maintained.

4. The rejection of claims 38-50 under 35 U.S.C. § 102(e) as being anticipated by McGill et al. (U.S. Patent No. 5,459,078) is overcome for the reasons argued by Applicants in the Response to Office Action received on May 11, 2000 (paper No. 10).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brecht et al. (Analitica Chimica Acta *311*, 289-299 **1995**), in view of Goddard et al. (Analyst *119*, 583-588, **1994**) for the reasons made of record in the Office Action mailed on September 3, 1999 (paper No. 7).

Applicants arguments have been fully considered and are not found persuasive for the following reasons.

Applicants traverse the rejection in the Response to Office Action received on May 11, 2000, on the grounds that Brecht et al. do not teach a laminar flow device.

However, this is not found persuasive for the reasons argued in paragraph 2 of the instant Office Action.

The rejection is maintained.

8. Claims 8, 10-12, 27-34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brecht et al., in view of Goddard et al. as applied to claim 7 above, and further in view of Beuchler et al. (U.S. Patent No. 5,458,852, October 17, 1995) in view of Finlan (U.S. Patent No. 5,055,265, October 8, 1991) for the reasons made of record in the Office Action mailed on September 3, 1999 (paper No. 7).

Applicants traverse the rejection in the Response to Office Action received on May 11, 2000, on the grounds that Brecht et al. do not teach a laminar flow device.

However, this is not found persuasive for the reasons argued in paragraph 2 of the instant Office Action.

The rejection is maintained.

New Grounds of Rejection

9. Claims 38-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brecht et al. (Anal. Chim. Acta *311*, 289-299, **1999**) in view of Goddard et al. (Analyst *119*, 583-588, **1994**) in light of Kimock et al. (U.S. Patent No. 5,637,353, June 10, 1997).

Claims 38 to 50 are drawn to a device wherein a diamond like carbon surface is used to support an attachment layer, wherein the attachment layer can host a number of biological receptor molecules, and the diamond like carbon can be applied by various techniques, resulting in various coating profiles..

Brecht et al. teach an analytical device that determines the concentration of an analyte through an indirect, competitive immunoassay. Brecht et al. demonstrate an assay for atrazine (a pesticide) where the difference in antibody concentrations between the control and sample are compared when the two samples selectively bind to an atrazine modified surface. The measurement is made by detecting a change in the mass properties or refractive index of the sensing surface. The cell of Brecht et al. uses a chemically modified-glass chip that is selective to the monoclonal anti-atrazine (i.e., support, optically functional layer, channel for sample flow, attachment layer, and analyte specific receptive layer). Brecht et al. clearly teach the advantage of an assay device that delivers the sample under laminar flow conditions compared an assay device that delivers the sample under "wall jet" (plug) flow conditions (see sections 3.3 and 3.4). Brecht et al. state (page 296):

> "Results (Fig. 7 anf Fig. 8) show clearly, that the signal can be increased by improvement of mass transport to the sensor surface... At least in part, the introduction of irregularities in flow characteristics affect not only the [test-to-test] reproducibility but also the noise of the binding curves."

Brecht et al. do not teach the use of an antireflective layer for improved sample analysis. Brecht et al., do not teach diamond like carbon.

Goddard et al. teach an optically-based biosensing device with improved analytical performance through integrating an antireflective coating. The resonant mirror is a planar waveguide optical sensor that uses frustrated total internal reflectance (first paragraph of page 584). Goddard et al. state (page 584):

> "It has been shown that the maximum sensitivity is reached when the refractive indices of the substrate and waveguide are as high as possible, and the refractive index of the spacer is as low as possible. This combination increases the fraction of light in the evanescent field, and hence increase the sensitivity."

The devices shown in Figure 1 and description thereof teach the optical relationships between various layers of such devices.

Kimock et al. discloses a substrate and method of making that provides the desired optical and mechanical properties with respect to a given use, wherein thin layer can be deposited by many different methods (see column 2, lines 1-30). The well-know properties of DLC coatings are disclosed, such as transparency, and high refractive index.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to follow the optical arrangement of Goddard et al., with the device of Brecht et al. as Goddard teaches optimized optical dimensions and properties for sensing devices that detect changes in the refractive index. Furthermore, one of skill in the art would have appreciated the use of DLC as Kimock et al. demonstrate the ease of deposition for a controlled substrate with a

high refractive index which is optically transparent. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

Conclusion

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren whose telephone number is (703) 306-3221. The Examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM (EST), and alternating Fridays from 8:00 AM to 4:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Michael Woodward, can be reached at (703) 308-4028.

Any inquiries of a general nature relating to this application should be directed to the Technical Center Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1631 using (703) 308-0294. Please notify the Examiner of incoming facsimiles prior to sending papers to the

aforementioned fax number. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Jeffrey S. Lundgren, Ph.D.

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER